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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,489	03/05/2002	Jean-Richard Neeser	112843-030	7111

24573 7590 09/15/2003
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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,489

Applicant(s)

NEESER ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 7-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The application should be reviewed for errors and conformity with domestic practice.

In keeping with scientific custom, the names of genera and species of microorganisms should be underlined or italicized throughout the specification and claims.

The election without traverse filed 7/11/03 is acknowledged. Claims 1-6 and 21-22 are being considered on the merits.

Claims 7-20 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 and 21-22 are rejected under 35 U.S.C. 101 because the claims read on the organism per se which is found in nature and thus, is unpatentable to applicant. Consequently, the claim does not embody patentable subject matter as defined in 35 USC 101. See, e.g., *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974); *American Fruit Growers v. Brogdex Co.*, 283 U.S. 1 (1931); *Funk Brothers Seed. Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948); *Diamond v. Chakrabarty*, 206 U.S.P.Q. 193 (1980).

It is suggested that applicant use the language "a biologically pure culture" in connection with the strain to identify a product that is not found in nature.

Rejections under 35 U.S.C § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a novel strain of *Lactobacillus*. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

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It appears that a deposit was made in this application as filed. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the

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availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 21-22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Guandalini *et al.* (WO 98/06411)

The claims are directed to a *Lactobacillus* bacterium capable of preventing colonization of the intestine with pathogenic bacteria causing diarrhea, in particular a *L. paracasei* strain. The reference discloses a *Lactobacillus* bacterium capable of preventing colonization of the intestine with pathogenic bacteria causing diarrhea, in particular a *L. paracasei* strain, as well as a food preparation thereof. See, e.g., Examples and page 6, lines 23-25.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Morelli *et al.* (WO 95/33046) in light of ATCC Catalogue.

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The claims are directed to a *Lactobacillus* bacterium capable of preventing colonization of the intestine with pathogenic bacteria causing diarrhea, in particular a *L. paracasei* strain. The reference discloses a *Lactobacillus* bacterium capable of preventing colonization of the intestine with pathogenic bacteria causing diarrhea. See, e.g., Examples.

The ATCC Catalogue adequately demonstrates that *L. paracasei* is so similar or closely related to *L. acidophilus* and *L. rhamnosus* to be substantially indistinguishable.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Pedraglio (EP 861905)

The claims are directed to a *Lactobacillus* bacterium capable of preventing colonization of the intestine with pathogenic bacteria causing diarrhea, in particular a *L. paracasei* strain. The reference discloses a *Lactobacillus* bacterium capable of preventing colonization of the intestine with pathogenic bacteria causing diarrhea, in particular a *L. paracasei* strain. See, e.g., Examples.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tuomola *et al.*.

The claims are directed to a *Lactobacillus* bacterium capable of preventing colonization of the intestine with pathogenic bacteria causing diarrhea, in particular a *L. paracasei* strain. The reference discloses a *Lactobacillus* bacterium capable of preventing colonization of the intestine with pathogenic bacteria causing diarrhea, in particular a *L. paracasei* strain. See, e.g., page 46, col. 1 and Table I, page 48.

Claims 1-3 and 21-22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Brassart *et al.* (U.S. Patent No. 5,603,930).

The claims are directed to a *Lactobacillus* bacterium capable of preventing colonization of the intestine with pathogenic bacteria causing diarrhea, in particular a *L. paracasei* strain. The reference discloses a *Lactobacillus* bacterium capable of preventing colonization of the intestine with pathogenic bacteria causing diarrhea, in particular a *L. paracasei* strain, as well as a food preparation thereof. See, e.g., Examples.

Claims 1-3 and 21-22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Casas *et al.* (U.S. Patent No. 5,837,238).

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The claims are directed to a *Lactobacillus* bacterium capable of preventing colonization of the intestine with pathogenic bacteria causing diarrhea..

The reference discloses a *Lactobacillus* bacterium capable of preventing colonization of the intestine with pathogenic bacteria causing diarrhea, as well as a food preparation thereof. See, e.g., col. 2, lines 35-54 and Examples.

Claim 6 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Guandalini *et al.* (WO 98/06411) or Pedraglio (EP 861905) or Tuomola *et al.* or Brassart *et al.*.

The claim is directed to a strain of *Lactobacillus paracasei* capable of preventing colonization of the intestine with pathogenic bacteria causing diarrhea.

As discussed the cited references each discloses a *Lactobacillus paracasei* which appears to be identical to the presently claimed strain since it capable of preventing colonization of the intestine with pathogenic bacteria causing diarrhea. The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism since it is similarly capable of preventing colonization of the intestine with pathogenic bacteria causing diarrhea. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

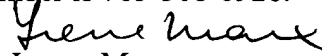
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 703-308-2922. The examiner can normally be reached on M-F (6:30-3:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0926.



Irene Marx

Primary Examiner

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